K023745

510(k) SUMMARY

JAN 17 2003

Device Name:

Classification Name: Breathing Gas Mixer
Common Name: Gas Mixer
Proprietary Name: Sechrist 3500CP-G Air/Oxygen Mixer

Devices to which Equivalence is Claimed:

K802226 Sechrist Air/Oxygen Mixer
K992503 Sechrist Air/Oxygen Mixer
K841789 Sechrist Air/Oxygen Mixer (Shiley, Inc.)
K863902 Modified Sarns Membrane Oxygenator (Sarns, Inc./3M)
K901253 (PBS) Portable Bypass System, Model 1000 Bio-Medicus

Contact:

Greg Godfrey, Vice President,
Quality Assurance & Regulatory Affairs
4225 E. La Palma Ave.
Anaheim, CA 92807
Phone: (714) 579-8400
Fax: (714) 579-0814

Indications for Use:

The intended use of the Sechrist Model 3500CP-G Air/Oxygen Mixer is to enable qualified personnel to mix medical grade air and medical grade oxygen at operator selected ratios, for delivery to patients through various types of respiratory care and heart bypass oxygenation equipment.

Device Description:

The Sechrist Model Series 3500CP-G Air/Oxygen Mixer is a precision pressure regulation and proportioning device which is intended to mix medical grade air and medical grade oxygen. The mixer receives pressurized air and oxygen, at a nominal 50 psi, via Diameter Index Safety System (D.I.S.S.) inlet connections. The unit will operate satisfactorily with inlet pressures of 30 to 70 psi, providing the pressures are within 20 psi of one another. Two outlets for the mixed gas are provided. The air/oxygen mixers are configured with zero to three flowmeters. Accessories include air and oxygen hoses.

Performance Standards:

A performance standard regulation under Section 514 of the Food, Drug and Cosmetic Act has not been promulgated for this device type. However, the device is designed and manufactured in accordance wit the following national and international standards:

ISO 9001 Quality Assurance Standard
ISO 13485 Quality System Standard, Medical Devices

510(k) SUMMARY

EN 46001 Application of ISO 9001 to manufacture of medical devices
21 CFR 820 Quality System Regulation

Summary of Substantial Equivalence:

The Sechrist 3500CP-G (3500/3500HL Model Series) was originally cleared under 510(k)'s K802226 and K992503 to mix Medical Grade Air and Medical Grade Oxygen at operator selected ratios, for delivery through various types of respiratory care equipment.

The indications for use were revised to include the use of the 3500CP-G Sechrist Air/Oxygen Mixer to provide mixed Medical Grade Air and Medical Grade Oxygen for cardiopulmonary bypass purposes. This use was previously cleared for the Sechrist Air/Oxygen Mixer under 510(k) Numbers K841789, by Shiley, Inc., K863902, by Sarns Inc., and K901253, Bio-Medicus.

Conclusion:

The device is substantially equivalent to the devices previously cleared under the above referenced 510(k) numbers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Sechrist Industries, Inc.
c/o Mr. Greg Godfrey
4225 E. La Palma Avenue
Anaheim, CA 92807

Re: K023745
Sechrist 3500CP-G Air/Oxygen Mixer
Regulation Number: 21 CFR 870.4300
Regulation Name: CPB Gas Control Unit
Regulatory Class: Class II (two)
Product Code: DTX
Dated: November 4, 2002
Received: November 7, 2002

Dear Mr. Godfrey:

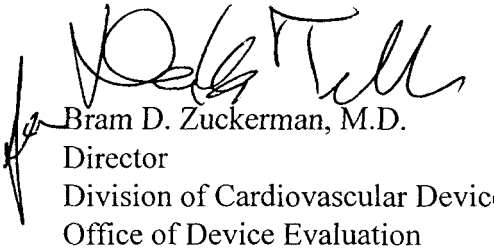
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Sechrist 3500CP-G Air/Oxygen Mixer

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter**
(Per 21 CFR 801.109

(Optional Format 1-1-96

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023745